



Office of Compliance and Enforcement

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Center for Tobacco Products
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Lexington, KY

Agenda

- FDA's Authority
- What FDA Tobacco Regulation Means
- Milestones
- About OCE
- Achieving Compliance
- Collaboration

FDA's Authority

- The Federal Food, Drug, and Cosmetic Act (FD&C Act) is the primary federal law for FDA
- The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) became law on June 22, 2009
 - The Tobacco Control Act amended the FD&C Act to give FDA authority to regulate the manufacture, distribution, and marketing of tobacco products to protect public health
 - Established the Center for Tobacco Products (CTP)

FDA's Authority

- FDA's statutory authority applies to all “tobacco products”
 - FDA currently regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco
 - FDA announced that it intends to issue a regulation to assert jurisdiction over all products that meet the definition of a “tobacco product”

FDA Tobacco Product Regulation:

- Contracting with state and local entities to perform retail compliance check inspections
- Requiring warnings for tobacco product packages and advertising
- Inspecting registered establishments who manufacture tobacco products
- Establishing tobacco product manufacturing practices
- Requiring tobacco product ingredient reporting
- Requiring testing and reporting of harmful and potentially harmful constituents

FDA Tobacco Product Regulation:

- Banning the manufacturing and sale of fruit or candy flavored cigarettes
- Restricting the use of “light,” “low,” or “mild,” or other similar descriptors in the labeling and advertising of tobacco products



Milestones

A more extensive list of Key Events and Tobacco Control Act Milestones can be found at:

www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm294279.htm

Milestones

- **September 2009**

Tobacco Control Act bans cigarettes with characterizing flavors such as fruit or candy



- **March 2010**

Published final rule restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents (reissued 1996 rule)



Milestones

- **June 2010**



Requirements for revised warning labels on smokeless tobacco product packages and advertisements took effect



Began awarding state enforcement contract



Restrictions on tobacco products labeled or advertised as “light”, “mild”, or “low” took effect

Milestones

- **October 2010**



Published Enforcement Action Plan for promotion and advertising restrictions, which covers the sale of menthol and other cigarettes to youth (especially in minority communities)

- **June 2011**



Published final regulation that will require graphics illustrating the negative health consequences of smoking. Graphics will accompany 9 new health warning statements that will appear on cigarette packages and in advertisements

Office of the Center Director

Office of Science

Office of Policy

Office of Health Communication and Education

Office of Compliance and Enforcement

Office of Regulations

Office of Management



Voluntary Compliance

Compliance Education / Information

Complaints

Investigations

Inspections

Enforcement Tools

Warning Letters

Civil Money Penalties
& No Tobacco Sale Orders

Seizures & Injunctions

Criminal
Prosecution

Compliance

Compliance Education & Information

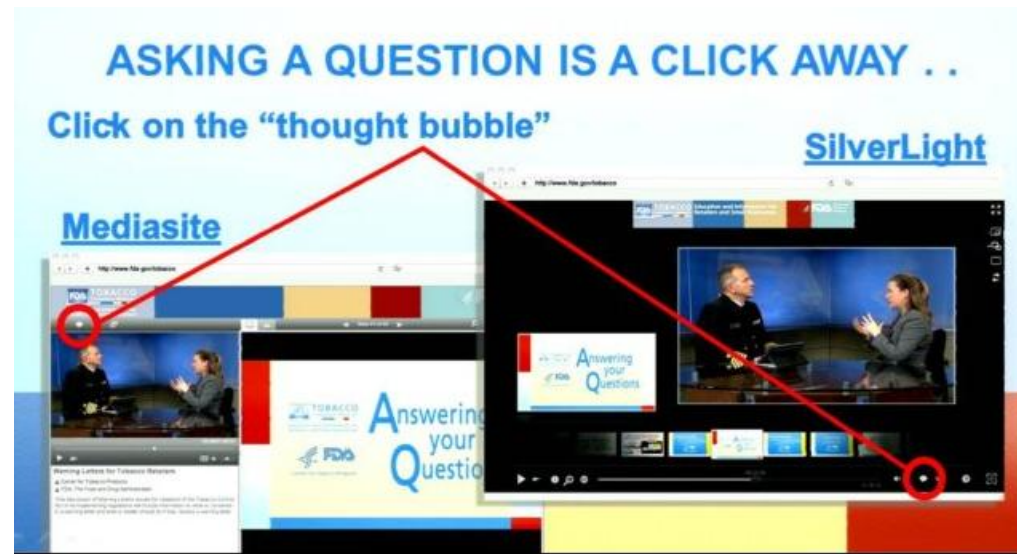
Encourage voluntary compliance by increasing regulated industry's awareness and knowledge of tobacco laws and regulations

- Webinars
- Guidance
- Retailer Educational Materials
- Stakeholder Engagement

Compliance Education and Information - Webinars



- Held monthly; opportunity to ask questions
- Intended audience includes retailers and small businesses
- Recent topics:
What to Expect During a Tobacco Retailer Inspection;
Warning letters
and CMP Update
- Sign up for notification – search
“Tobacco Compliance Webinars”



Compliance Education & Information - Guidance

- How FDA publicly communicates to industry recommendations for complying with the law and regulations
- Ensures FDA provides consistent advice and information for stakeholders
- Not legally binding

Compliance Education & Information - Guidance

- Draft Guidance
 - An opportunity for stakeholders to participate in the regulatory process by submitting comments, data, and other information
 - Time period for comments is specified, however comments can be submitted at any time, even after a docket is closed

Compliance Education & Information - Guidance

- Comments are received from groups such as
 - Regulated industry
 - Researchers and academics
 - Public health organizations
 - Other Federal government agencies
 - State, local and tribal governments
 - General public
- FDA will consider all comments before issuing a final guidance
- Copies of all guidances are found on our website

Compliance Education & Information - Guidance

Guidances relevant to tobacco retailers include:

- Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers
- General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2)
- Tobacco Retailer Training Programs
- Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents
- Guidances can be found on our website at:

www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm281147.htm

Compliance Education & Information – Retailer Education Materials



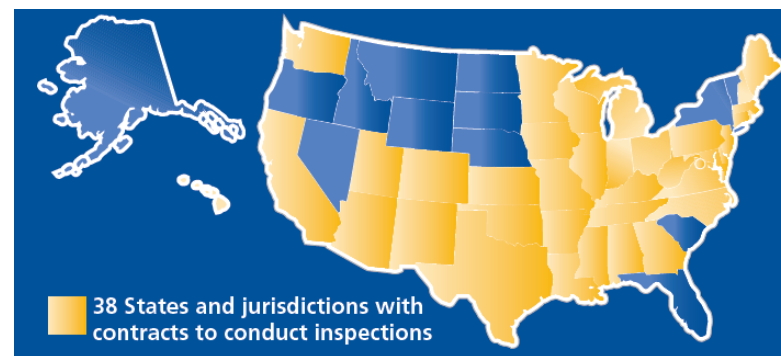
- The Break the Chain of Tobacco Addiction campaign educates retailers about tobacco product regulations.
- Visit www.fda.gov/tobacco materials to order or download free materials. If you would like to order more than the maximum quantity allowed, please send your request to FDAtobaccomaterials@fda.hhs.gov.

Complaints

- FDA strongly encourages anyone, including members of the public, to report potential violations
- FDA reviews each complaint received from any source. FDA conducts its own investigation regarding potential violations that are reported.
- CTPCompliance@fda.hhs.gov
1-877-CTP 1373

Inspections

- FDA has authority to inspect establishments engaged in the manufacture, preparation, compounding, or processing of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco
- FDA also has authority to contract with States, Territories, and Tribes to assist FDA with performing compliance check inspections of tobacco retailers



More information about FDA Tobacco Retail Inspection Contracts at <http://go.usa.gov/UvH>

Tobacco Retailer Inspections

What Happens During a Tobacco Retailer Compliance Check Inspection?

- Minor attempts to purchase cigarettes, smokeless tobacco, or roll-your-own tobacco to determine whether the retailer checks the photo ID with date of birth of anyone under age 27 and does not sell the tobacco product to the minor

Tobacco Retailer Inspections

The inspector will be checking, among other things, if the retailer:

- Only sells cigarettes, smokeless tobacco, and roll-your-own tobacco in a direct, face-to-face exchange. (The only exception is vending machines and self-service displays located in facilities or locations where no person younger than 18 is present or permitted to enter at any time)
- Gives away free samples of cigarettes
- Breaks open cigarette or smokeless tobacco packages to sell products in smaller amounts
- Sells single cigarettes (also called “loosies”)

Tobacco Retailer Inspections

The inspector will also be checking, among other things, if the retailer:

- Sells cigarette packages containing fewer than 20 cigarettes
- Offers free samples of smokeless tobacco except in a “qualified adult-only facility”
- Sells or gives away items — such as hats, t-shirts, or lighters — with tobacco brands or logos
- Sells flavored cigarettes or flavored cigarette tobacco
 - Exception: menthol flavored cigarettes or menthol flavored cigarette tobacco

Tobacco Retailer Inspections

- Inspectors provide inspection data and evidence to FDA
- FDA reviews the inspectional evidence and determines if a violation occurred
- If a violation occurred, FDA undertakes enforcement action (i.e. issues a warning letter (WL) or a civil money penalty (CMP))
- FDA posts all WLs and CMPs issued to retailers



Database: Compliance Check Inspections of Tobacco Product Retailers

Compliance Check Inspections of Tobacco Product Retailers (through 02/29/2012)

[FDA Home](#) [Tobacco Products](#) [Information about Compliance Check Inspections](#)

Decision Type

Decision Date

Date Format: mm/dd/yyyy.
For example: 05/01/2011

Search Inspection Decisions [Help](#)

Retailer Name

City

State Zip

Decision Type

Decision Date to

Date Format: mm/dd/yyyy.
For example: 05/01/2011

Records per Report Page

[Export All Data to Excel](#)

Enforcement Tools

- *Warning Letters*
- *Civil Money Penalty Complaints*
- No Tobacco Sale Orders
- Seizures
- Injunctions
- Criminal Prosecution

Warning Letters

- A Warning Letter is an agency advisory action used to achieve compliance
- A Warning Letter gives the recipient notice of a violation in their establishment
- A Warning Letter warns the recipient that their failure to correct the violation may result in further enforcement action by FDA (i.e. CMP or No Tobacco Sale Order)

Warning Letters

- Warning Letters contain a description of each violation observed and the evidence obtained to support the charge(s)
- FDA issues a Warning Letter the first time an FDA tobacco compliance check inspection at a retailer reveals a violation
- FDA requests a response to the Warning Letter within 15 days

Warning Letters

- After a retailer receives a Warning Letter, FDA conducts a follow-up compliance check inspection at that retail establishment without further notice
- If FDA identifies any violation during a follow-up compliance check inspection at that retail establishment, FDA seeks a Civil Money Penalty through issuing an Administrative Complaint to the tobacco retailer

Enforcement

Since its inception, the FDA Tobacco Retail Inspection program has issued over*:

- 2,429 Warning Letters
- 101 Civil Money Penalty Complaints

FDA currently has contracts with 37 States and the District of Columbia. FDA is currently reviewing applications in response to a recent RFP and expects more states and territories to contract with

Kentucky *

- Started inspections October 10/11
- 1280 inspections completed
- 1256 inspections: No violations observed
- 24 warning letters issued

* Data through 3/31/12

Kentucky – Warning Letters

Examples of violations found in Kentucky:

- Sale of cigarettes or smokeless tobacco to minor under age 18
- Failure to ask for photo ID with DOB
- Impersonal modes of sale in facilities where children <18 present/permitted
- Free samples
- Sale of single cigarettes

Collaboration

You can help support FDA's mission:

- Disseminate information about, and submit comments to relevant dockets, TPSAC meetings, draft guidances, and regulations
- Share information with FDA about new or unique tobacco products, advertising, or marketing promotions
- Inform FDA about important changes in your state's tobacco control policy
- Disseminate information about FDA's compliance outreach efforts (webinars)
- Report potential tobacco violations to the Center



Collaboration

CTP will support you...

- Collaborating with Synar to ensure that the separate programs work together to help reach the shared goal of reducing youth access to and use of tobacco products

A Strategic Partnership

The Food and Drug Administration's (FDA) Tobacco Retail Compliance Inspection Contracts and the Substance Abuse and Mental Health Services Administration's (SAMHSA) Synar Program

In July 1992, the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (P.L. 102-321) became law, which includes the Synar amendment (section 1926) aimed at decreasing youth access to tobacco.

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) became law granting the Food and Drug Administration (FDA) authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Currently the law applies to cigarettes, smokeless tobacco and cigarette tobacco.

SAMHSA and FDA are collaborating to ensure that their separate programs work together to help reach the shared goal of reducing youth access to, and use of, tobacco products.

Overview of Programs

FDA's Tobacco Retail Compliance Inspection Contracts	SAMHSA's Synar Program
<p>The Tobacco Control Act authorizes FDA to contract, where feasible, with States, the District of Columbia, five U.S. Territories (American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, Palau, Puerto Rico, and the U.S. Virgin Islands), and American Indian Tribes to assist with inspections of retail establishments.</p> <p>Section 102 of the Tobacco Control Act required FDA to re-issue its 1998 final regulation restricting the sale and distribution of cigarettes and smokeless tobacco products. The rule contains provisions designed to limit young people's access to tobacco products, as well as restrictions on marketing to curb the appeal of these products to minors. The youth access and advertising regulations took effect on June 22, 2010 (21 C.F.R. Part 1140).</p>	<p>The Synar regulation is applicable to the 50 States, the District of Columbia, and eight U.S. Territories (American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, Palau, Puerto Rico, and the U.S. Virgin Islands). It is not applicable to American Indian Tribes.</p> <p>The Synar regulation requires States and U.S. Territories (as a condition of receiving their full Substance Abuse Prevention and Treatment Block Grant (SAPT BG) awards) to:</p> <ul style="list-style-type: none"> • Have in effect a law prohibiting any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any individual younger than age 18; • Enforce this law; • Conduct annual, unannounced inspections of retail tobacco outlets in a way that provides a valid probability sample of tobacco sales outlets accessible to minors; • Negotiate interim target rates and a date to achieve a noncompliance rate of no more than 20 percent; and • Submit an annual report detailing State and Territorial activities to enforce its law.

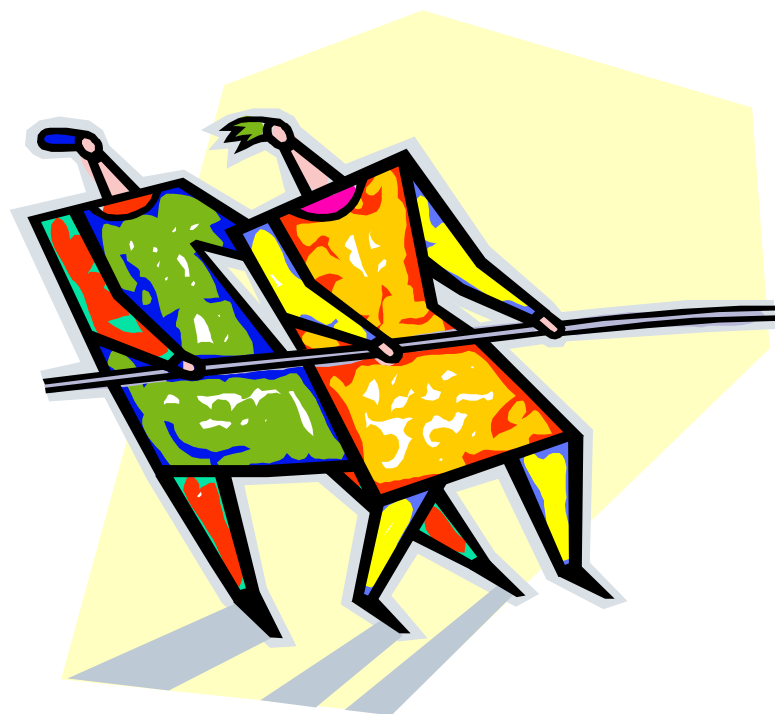


Collaboration

Resources to help you stay informed

- www.fda.gov/tobacco
- *Via our Call Center: 1-877-287-1373*
- *Email: askctp@fda.hhs.gov*
- *Via our Ombudsman: les.weinstein@fda.hhs.gov*
- Twitter: @FDATobacco
- Widgets and Content Syndication (<http://tools.fda.gov>)
- CTP Site in Spanish (www.fda.gov/tabaco)
- *This Week in CTP* and other E-mail subscriptions
- Mobile applications (*Coming Soon*)

FDA & You



Working together to
reduce the morbidity
and mortality from
tobacco use